

#### **REMARKS**

Claims 34, 35, 38, 40-41 and 74, 75, 77-81 are pending. Claims 40, 41, 74, 75, 78, and 79 are amended. Claims 36 and 76 are canceled without prejudice or disclaimer. Applicants hereby expressly reserve the right to pursue one or both of claims 36 and 76 in one or more divisional and/or continuation applications hereof.

Claims 40, 41, 74, 75, 78, and 79 are amended make grammatical corrections and recite proper antecedent basis. No new matter enters by these amendments.

#### **Information Disclosure Statement**

Applicants are submitting herewith an Information Disclosure Statement ("IDS"). The references cited in the IDS have been submitted and considered in applications of the same family as the present application, i.e., in applications that have at least one application in common in their claim of priority with the present application.

While the information and references disclosed in the Information Disclosure Statement are submitted pursuant to 37 C.F.R. § 1.56, the submission is not intended to constitute an admission that any patent, publication or other information referred to is "prior art" to this invention. The references disclosed may be less relevant than other references and/or may be cumulative of art now known or otherwise cited to the Office.

#### **Rejections under 35 U.S.C. § 103**

**Claims 34-36, 38 and 74-77 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Saul (US 5,868,743) in combination with Chen (US 5,782,828) and Lesh (US 6,164,283).**

The Supreme Court's ruling in *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 USPQ2d 1385 (2007), and recent PTO guidance associated with it, has made explicitly

clear that at least one aspect of an obviousness rejection has not changed: the initial burden remains on the Examiner to detail the findings of fact and rationale that support a rejection based on obviousness under section 103. Indeed, “[r]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” MPEP § 2141 (citing *KSR*, 127 S.Ct. at 1741). The Patent Office’s guidelines make clear that “the key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.” *Id.* Applicants respectfully assert that the rejections posed have wholly failed to reach the minimum threshold, or burden of proof, which the Examiner must satisfy to establish a *prima facie* case of obviousness.

The Examiner makes the conclusory assertion that “Saul et al teaches a method such as claimed except epicardial placement.” Office action, at p. 2. Yet the Examiner provides no citations, except a broad reference to one of the examples, to specifically identify where each of the claim limitations, aside from epicardial placement, are allegedly taught in Saul. Applicants respectfully request that the Examiner identify, for each claim, where each element of the claimed invention is taught in the cited references.

Applicants contend that Saul fails to discuss or suggest a number of elements of the claimed invention aside from epicardial placement. For example, Saul fails to discuss or suggest at least the following elements of independent claim 34:

- analyzing the temperature change over the first period of time to determine a temperature response of tissue at the tissue site;
- characterizing the tissue based on the temperature response of the tissue, wherein the characterizing step consists of at least one of comparing the temperature response with temperature responses of other known tissue types and considering the input of at least one variable from a list of

variables consisting of presence of fat, amount of fat, flow rate of blood, tissue thickness and temperature of blood; and

- determining an ablation time interval and a desired temperature to be delivered by the ablating element based on the tissue characterization.

Likewise, Saul neither discusses nor suggests at least the following elements of independent claim 74:

- analyzing the temperature change to determine a tissue characterization;
- activating the ablating element after the analyzing step is completed; and
- ablating tissue at the tissue site with a second quantity of energy over a second period of time, wherein the ablating step is carried out with input from at least one variable from a list of variables consisting of presence of fat, amount of fat, flow rate of blood, tissue thickness and temperature of blood.

Applicants respectfully assert that nowhere does Saul teach or suggest the methods of the present invention, in particular methods that include analyzing a temperature change to characterize the tissue and using the tissue characterization to determine appropriate ablation parameters. Saul discusses a method for identifying “a preponderance of true positive conduction sites” by applying a “test application” at a low or non-damaging temperature. (Saul, col. 2:66 – 3:4). If conduction block is observed after the low temperature application, it is followed by a high temperature application. If conduction block is not observed after the low temperature application, the site is deemed ineffective for permanent block and a different site is tested. (Saul, col. 3:21-29). There is no other information on the tissue used or considered by the methods in Saul.

Nowhere does Saul discuss analyzing a temperature change to determine a tissue response and characterizing the tissue based on input from at least one variable,

such as presence of fat, amount of fat, flow rate of blood, tissue thickness and temperature of blood, and determining appropriate ablation parameters based on the tissue characterization, as recited in claim 34. Nor does Saul discuss analyzing a temperature change to determine a tissue characterization, activating the ablating element after the analyzing step is completed, and ablating tissue with a second quantity of energy over a second period of time based on input from at least one variable, such as presence of fat, amount of fat, flow rate of blood, tissue thickness and temperature of blood, as recited in claim 74.

The addition of Chen and Lesh do not remedy these deficiencies. The Examiner asserts that "Chen teaches the desirability of ablating on the epicardium or the endocardium," and that "Lesh teaches the necessity of making transmural lesions to provide conduction block." Office action, at p. 2. Nevertheless, Applications respectfully assert that neither Chen nor Lesh discusses or suggests the deficiencies noted above with respect to Saul, in particular, the steps of analyzing the temperature change over time to determine a temperature response, characterizing the tissue based on the temperature response based on input of at least one variable from a list of variables consisting of presence of fat, amount of fat, flow rate of blood, tissue thickness and temperature of blood and/or comparing the temperature response with temperature responses of other known tissue types, and determining an ablation time interval and a desired temperature to be delivered by the ablating element based on the tissue characterization, as recited in claims 34 and 74. Therefore, the combination of Saul, Chen and Lesh does not teach, suggest, or render obvious Applicants' claimed invention.

For at least these reasons, Applicants' respectfully submit that a *prima facie* case of obviousness has not been made and request that the Examiner withdrawal the rejection of claims 34 and 74 and those claims that depend from claims 34 and 74.

**Claims 40 and 78 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Saul in combination with Chen and Lesh, and further in view of Swanson (US 6,142,994).**

Applicants have argued above that Saul in combination with Chen and Lesh do not teach, suggest, or render obvious claims 34 and 74, from which claims 40 and 78 depend.

The Examiner additionally alleges that "Swanson et al teaches the desirability of ablating on the epicardium and that less than half the total number of electrodes can be used." Office action, at p. 3. However, at a minimum, the addition of Swanson does not overcome the deficiencies argued above with respect to the other limitations of claims 34 and 74. Applicants respectfully submit that the Examiner has not met the burden of establishing a *prima facie* case that independent claims 34 and 74 are obvious over the combination of Saul, Chen and Lesh; therefore, dependent claims 40 and 78 are non-obvious over the cited references. MPEP § 2143.03; *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) ("If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious.").

Applicants respectfully request withdrawal of this rejection.

**Claims 41 and 79 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Saul in combination with Chen and Lesh, and further in view of Ben-Haim (US 6,171,303).**

Applicants have argued above that Saul in combination with Chen and Lesh do not teach, suggest, or render obvious claims 34 and 74, from which claims 41 and 79 depend.

The Examiner alleges that "Ben Haim teaches drawing tissue into a suction well prior to ablation." Office action, at p. 3. However, Ben Haim does not discuss or

suggest a device comprising "a plurality of ablating elements and a plurality of suction wells, wherein at least one of the ablating elements is positioned in each of the suction wells" as recited in claims 41 and 79. As shown in Figure 4A, Ben-Haim discusses a device having a single suction lumen. Further, there is no ablating element in the lumen 78 or the orifice 80 through which suction is provided. See Ben-Haim, Fig. 4A and col. 17:3-11. Thus, Ben-Haim fails to teach or suggest all of the claim elements.

Moreover, at a minimum, the addition of Ben-Haim does not overcome the deficiencies argued above with respect to the other limitations required by claims 34 and 74. Applicants respectfully submit that the Examiner has not met the burden of establishing a *prima facie* case that independent claims 34 and 74 are obvious over the combination of Saul, Chen and Lesh; therefore, dependent claims 41 and 79 are also non-obvious over the cited references. MPEP § 2143.03; *In re Fine*, 837 F.2d at 1076 ("If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious.").

For at least these reasons, Applicants respectfully request withdrawal of this rejection.

**Claims 80 and 81 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Saul in combination with Chen and Lesh, and further in view of He (US 6,423,057).**

Applicants have argued above that Saul in combination with Chen and Lesh do not teach, suggest, or render obvious claim 74, from which claims 80 and 81 depend.

The Examiner alleges that "He et al teaches determining tissue parameters by cooling the tissue. It would have been obvious to employ the device for and step of cooling the tissue since this is the equivalent to the use of heating energy to do so, as taught by He et al, thus producing a method and device such as claimed." Office action, at pp. 3-4. However, at a minimum, the addition of He does not overcome the

deficiencies argued above with respect to the other limitations required by claim 74. Applicants respectfully submit that the Examiner has not met the burden of establishing a *prima facie* case that independent claim 74 is obvious over the combination of Saul, Chen and Lesh; therefore, dependent claims 80 and 81 are also non-obvious over the cited references. MPEP § 2143.03; *In re Fine*, 837 F.2d at 1076 ("If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious.").

Additionally, and independently of the reasons argued above, the cited references do not teach or suggest that the use of cooling energy as recited in the claims, and particularly the characterizing tissue aspects. In particular, Saul is deficient in this regard. Saul explicitly states that it was based on the "discovery" that certain quantities of non-ablating heating energy can "stun" the target tissue and block accessory pathways. There is no teaching or suggestion in any of the cited documents that this "discovery" holds true for the application of cooling energy. Applicants respectfully submit that the Examiner has not met his burden of showing that cooling energy is equivalent to heating energy in the cited documents or why one of skill in the art would expect equivalent results.

For at least these reasons, Applicants respectfully request withdrawal of this rejection.

**CONCLUSION**

Applicants submit that the application is in condition for allowance. Timely notification of allowability is respectfully requested.

No fees, requests for extension of time, other petitions, additional claim fees, or any other fees are believed to be necessary to enter and consider this paper. If, however, any extensions of time are required or any fees are due in order to enter or consider this paper or enter or consider any paper accompanying this paper, including fees for net addition of claims, Applicants hereby request any extensions or petitions necessary. The Commissioner is hereby authorized to charge Deposit Account No. 50-1129 for any fees. If there is any variance between the fee submitted and any fee required, or if the payment or fee payment information has been misplaced or is somehow insufficient to provide payment, the Commissioner is hereby authorized to charge or credit Deposit Account No. 50-1129.

Respectfully submitted,

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